July 31, 2017

Michelle Ramirez
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
P.O. Box 4010, MS-12B
Sacramento, CA 95812-4010
Submitted Via https://oehha.ca.gov/comments

Re: Notice of Intent to List Tetrabromobisphenol A

Dear Ms. Ramirez:

The American Chemistry Council[1] (ACC) North American Flame Retardant Alliance (NAFRA)[2] appreciates this opportunity to provide comments to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) June 30, 2017 notice of intent to list Tetrabromobisphenol A (TBBPA) as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). OEHHA has indicated that it intends to list TBBPA pursuant to the Labor Code listing mechanism which requires that certain substances identified by the International Agency for Research on Cancer (IARC) be listed as known to cause cancer under Proposition 65.

In February 2017, IARC conducted a meeting to evaluate TBBPA and classified it as group 2A "probably carcinogenic to humans." While this IARC designation supports OEHHA's intent to list under the Labor Code mechanism, there are additional factors that OEHHA should take into consideration prior to moving forward. First, it is important to note that assessments of TBBPA conducted in both Canada[3] and the European Union[4] that have considered real-world exposure

[1] ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $768 billion enterprise and a key element of the nation's economy. Chemistry companies are among the largest investors in research and development, investing $91 billion in 2016.

[2] The American Chemistry Council's North American Flame Retardant Alliance was formed in March 2011. NAFRA represents major producers of flame retardants. For more information on NAFRA, please visit: http://flameretardants.americanchemistry.com/.

[3] Environment Canada and Health Canada. 2013. Screening Assessment Report Phenol, 4,4'-(1-methylethylidene) bis[2,6-dibromo-, Ethanol,2,2' [(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxy]]bis, Benzene, 1,1'-(1-methylethylidene)bis[3,5-dibromo-4-(2-propenyloxy)-, Available at: http://ec.gc.ca/ese-ees/BEE093E4-8387-4790-A9CD-C753B3E5BFAD/FSAR_TBBPA_EN.pdf.

[4] European Chemicals Bureau. 2006. European Union Risk Assessment Report. 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol-A or TBBP-A) Part II –human health, Available at URL: http://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd51.

scenarios have found that consumer exposures to TBBPA are not likely to cause adverse human health effects. Secondly, IARC monographs are designed to identify a cancer hazard but not the potential risk expected from exposure to the hazard. The distinction between hazard and risk is critically important. For example, in the case of TBBPA, IARC identified it as a cancer hazard even when the risks are very low at current exposure levels. One objective of Proposition 65 is to enable Californians to make decisions about protecting themselves from exposure to chemicals. This means that both hazard and the potential for human exposure need to be considered in order to enable informed decision-making regarding risk.

The current published scientific literature contains information for TBBPA that provides an estimate of daily oral exposures to the human population that are likely to be without an appreciable risk[5]. These values take into consideration plausible human health exposure scenarios and the available toxicity data. Utilizing this information in the development of no significant risk levels is one approach to ensure that hazard and risk have been considered. This is critical for OEHHA's listing of TBBPA. TBBPA is used primarily as a reacted component (i.e. molecularly bonded into the matrix of a treated polymer), and to a much lesser extent as an additive component (i.e. physically combined with the material). TBBPA that is used in a reactive application where it is transformed into a polymer resin, predominantly no longer exists and is therefore not available to migrate out of the product. Additionally, this polymer resin is typically in parts that are not readily accessible or handled by consumers.

When considering TBBPA for listing, OEHHA should evaluate current possible exposure pathways for reactive and additive TBBPA and the limited likelihood of human exposure to reacted TBBPA. As such, we would recommend that any future listing of TBBPA be limited only to additive TBBPA uses. NAFRA would welcome the opportunity to meet with OEHHA staff to discuss the available TBBPA data, differences between reactive and additive exposures, and the establishment of a no significant risk level. We look forward to your response to this letter and meeting with your staff in the future. Feel free to contact me by email (kimberly_white@americanchemistry.com) or phone (202-249-6707) or with any questions related to this letter.

Respectfully Submitted,

Kimberly Wise White, PhD
American Chemistry Council (ACC)
Senior Director
Chemical Products & Technology Division
On Behalf of the ACC North American Flame Retardant Alliance

[5] Wikoff, D, Thompson, C, Perry, C, White, M, Borghoff, S, Fitzgerald, L, and Haws, LC. (2015). Development of toxicity values and exposure estimates for tetrabromobisphenol A: application in a margin of exposure assessment. J Applied Toxicol. 35(11):1292-1308